**REMARKS**

Following this response, claims 27-36 and 47-50 are pending in this application. Claims 1-26, 37-26, and 51 have been withdrawn by the Examiner. Claims 27-36 and 47-50 presently stand rejected. Claims 27 and 47 are presently amended. In view of these amendments and the discussion below, it is submitted that the application is now in condition for allowance.

**Claim Rejections 35 U.S.C. § 102**

The Examiner has rejected claims 27-36 and 47-50 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,687,662 (Schobel). In particular, the Examiner points to column 3, lines 10-12, and the abstract of Schobel, and states that Schobel discloses a method for oral administration of an effervescent composition in the form of tablets or powders including a therapeutic agent, a granulating agent, a microparticulate effervescent component and an effervescent system that dissolve rapidly in water to yield an effervescent solution containing a completely dissolved therapeutic agent. The Examiner further states that the granulating agent of Schobel causes slow disintegration of the therapeutic agent and release of gas (citing column 4, lines 17-28), and that the effervescent system includes compounds capable of reacting with carbonate containing materials to cause the release of carbon dioxide when contacted with sufficient water (citing column 5, lines 14-18 and lines 45 et seq.). Applicants respectfully disagree.

As an initial matter, Applicants note that independent claims 27 and 47 (the only independent claims presently being examined) each require a solid ingestible pharmaceutical composition having (1) "a gas-dispersing component including a solid matrix having at least one first gas contained therein," and (2) "a gas-generating effervescent component," having components that react with an aqueous vehicle to generate "a second gas." Applicants submit that Schobel does not disclose both a gas-dispersing component including a solid matrix having a first gas contained therein and an effervescent component that generates a second gas.

In particular, Applicants submit that Schobel only discloses an effervescent system that generates one gas. As described at column 2, lines 20-27, the composition of Schobel includes (1) a preblended mixture of (a) a granulated therapeutic agent and (b) a component of an effervescent system; and (2) other components of the effervescent system. In the preblended mixture, the granulated therapeutic agent and the component of the effervescent system (which is described in Schobel as being a "microparticulate acid") are of roughly similar size (the granulated therapeutic agent being between 100-600 microns and the microparticulate acid being 50-600 microns).

The Examiner points to column 4, lines 17-28 of Schobel, stating that the granulating agent causes a release of gas. The Examiner then points to column 5, lines 14-18 and 45 et seq., stating that the effervescent system causes the release of carbon

dioxide. Thus, here, the Examiner makes the argument that the composition of Schobel releases both a first gas (caused by the granulating agent) and a second gas (caused by the effervescent system). Applicants submit that the Examiner's characterization of Schobel is incorrect.

In particular, Applicants submit that the Examiner's statement that the granulating agent of Schobel causes a release of gas is incorrect. To that end, column 4, lines 17-28 (cited by the Examiner as teaching that the granulating agent of Schobel causes the release of a gas) state the following:

> "The granulating agent may be selected from the group consisting of water, alcohol, polyvinylpyrrolidone, sucrose, hydroxypropyl cellulose and mixtures thereof. The preferred granulating agent for use in the instant invention is polyvinylpyrrolidone."
>
> "The granulating agent is present in the instant invention in an amount from about 0.03 to about 2.5% by weight. Less than about 0.03% granulating agent causes a residue of surface film containing undissolved therapeutic agent to form. Greater than about 2.5% causes slow disintegration."

Applicants submit that the first paragraph of this quote simply teaches various materials that can be used as the granulating agent in Schobel. Applicants further submit that the second paragraph of this quote merely teaches a preferred range of amount of granulating agent (with the admonition that amounts of granulating agent less than or greater than the stated preferred range will obviate the advantages obtained by the particularly disclosed composition of Schobel). Applicants submit that the important

point, however, is that this quote does not teach or suggest that the granulating agent causes the release of a gas. In fact, Applicants submit that nowhere does Schobel teach that the granulating agent causes a release of any gas.

What Schobel does teach about a gas can be found at column 5, lines 14-18 and 45-64 (cited by the Examiner in the Office Action). There, Schobel teaches that the effervescent system that is used to aid in solubilizing the granulated therapeutic agent into an aqueous solution, includes "microparticulate acids," which are capable of reacting with carbonate-containing materials to cause the release of carbon dioxide when contacted with a sufficient amount of water. As described above, in Schobel, a granulated therapeutic agent (of 100-600 microns) and microparticulate acids (of 50-600 microns) are admixed to form a preblended mixture. The microparticulate acids are one component of the effervescent system. The remainder of the effervescent system includes all the ingredients of a rapid-dissolving effervescent composition, except for the microparticulate acids as stated at column 5, lines 43-45. And in particular, at column 5, lines 45-64, Schobel describes that the remainder of that effervescent system uses carbonate-containing materials. The various components of the Schobel composition (the preblended mixture of therapeutic agent and microparticulate acid, and the carbonate-containing materials of the remainder of the effervescent system) can then be formed into a desirable shape, such as a tablet, to render a final product.

In use, this tablet is added to an aqueous environment (such as water), causing the microparticulate acids to react with the carbonate-containing materials to release carbon dioxide. However, this carbon dioxide gas is the only gas generated or released during use of the composition disclosed by Schobel. Nowhere in Schobel is any other gas disclosed, nor is any other component disclosed in Schobel that would generate another gas. Thus, Applicants submit that Schobel does not disclose a solid ingestible pharmaceutical composition including "a gas-dispersing component including a solid matrix having at least one first gas contained therein," as is recited in independent claims 27 and 47 of the present application. As such, Applicants respectfully assert that Schobel does not anticipate independent claims 27 or 47 (or any of their dependent claims 28-36 and 48-50).

The Examiner has further rejected claims 27-36 and 47-50 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,223,264 (Wehling). The Examiner states that Wehling discloses a method for oral administration of oral effervescent dosage forms including a mixture of at least one effervescent disintegrating agent, and a pediatrically effective amount of at least one intended ingredient in the form of a tablet. The Examiner further states that the effervescent agent of Wehling includes compounds that evolve gas by means of chemical reactions, which takes place upon exposure of the effervescent agent to produce carbon dioxide, oxygen, or other

gases upon contact with water including saliva or simple gastric fluids. Applicants respectfully disagree.

Like Schobel, Applicants submit that Wehling also does not disclose "a gas-dispersing component including a solid matrix having at least one first gas contained therein," as is recited in independent claims 27 and 47 of the present application. Like Schobel, Wehling simply discloses an effervescent formulation including a medicament in tablet form, wherein that tablet also includes effervescing components. In particular, Wehling includes "effervescent disintegration agents," which include compounds that evolve a gas. As described at column 3, lines 10-17 of Wehling, the effervescent disintegration agent includes one acid and at least one base, the base being selected from the group consisting of carbonate salts, bicarbonate salts, and mixtures thereof. The acids and bases of the effervescent disintegration agent are water-activated materials. And thus, the composition of Wehling may be provided in a tablet form and added to an aqueous vehicle, such as water. When the tablet contacts the water, the acids and bases of the effervescent disintegration agents react to produce carbon dioxide gas. At column 5, lines 38-42, Wehling allows that an alternate gas, such as oxygen, can be evolved from reactants of the effervescent disintegration agents. However, nowhere does Wehling suggest that two separate gases are included in or generated by the composition of Wehling. Only the single gas (carbon dioxide or oxygen) generated by the effervescent disintegration agent of the composition of

Wehling is present in Wehling. Thus, Wehling does not include both (1) a gas-dispersing component including a solid matrix having at least one first gas contained therein, and (2) a gas-generating effervescent component including components reactive with an aqueous vehicle to generate a second gas. In particular, Wehling does not include the solid matrix having at least a first gas contained therein. Such a solid matrix and first gas is recited in both independent claims 27 and 47, and thus all of their dependent claims. As such, Wehling does not anticipate either claim 27 (or its dependent claims 28-36) or independent claim 47 (or its dependent claims 48-50).

In view of the above, Applicants respectfully request a withdrawal of the rejections of claims 26-37 and 47-50 under 35 U.S.C. § 102(b) over both Schobel and Wehling.

**Conclusion**

For the foregoing reasons, it is submitted that all claims are patentable, and a Notice of Allowance is respectfully requested.

Please consider this paper to be a Petition for an Extension of Time of three months. A fee of $510.00 under 37 C.F.R. § 1.17(a)(3) is believed due as a result of this Petition. Any deficiencies or credits necessary to complete this communication should be applied to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,
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